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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,626	08/05/2003	Gregory M. Glenn	056707-5009-01	6381
9629 7590 01/03/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER KIM, YUNSOO	
			ART UNIT 1644	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/03/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/633,626	<b>Applicant(s)</b> GLENN ET AL.	
	<b>Examiner</b> Yunsoo Kim	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 61-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/06 has been entered.
2. Claims 1-60 have been canceled.  
Claims 61-97 have been added and are pending.
3. In view of Declaration by Dr. Gregory Glenn on 10/10/06, the rejection under 35U.S.C.112, first paragraph has been withdrawn.
4. The following new grounds of rejections are necessitated by Applicants' addition of new claims filed 10/10/06.
5. 35 U.S.C. 101 reads as follows:  
  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
6. Claims 61, 65, 67, 70, 73, 74, 81-83 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 76, 79, 80, 82-84, 87-89 of copending Application No. 11/143,942. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.
7. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1644

8. Claims 63, 68, 69, 75-77 and 81-97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification and the claims as originally filed do not provide a clear support for the phrases "a chemical conjugate" as in claim 63, "virus expresses a glycoprotein" in claim 68, "genetically detoxified toxins, chemically conjugated" in claim 75, "comprising pretreating the skin" in claim 81 and "sucrose and trehalose" as in claim 94. Applicant has not pointed out where the support comes from.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 61-75, 77-97 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 5,910,306 (IDS ref. VL, of record).

The '306 patent teaches a method of inducing immune response (claims 1-8, in particular) comprising formulation comprising an antigen and adjuvant (i.e. liposome encapsulating antigen and adjuvant, col. 4, lines 58-60, in particular).

As the '306 patent further teaches the liposome containing antigen and adjuvant can be lyophilized (i.e. dry form col. 4, lines 28-35, col. 12, example 2, in particular) and application of said formulation to skin of subject (col. 2, lines 64-65, in particular), the application of dry formulation is encompassed.

The '306 patent further teaches the use of occlusive dressing such as rayon covering the surface area larger than draining lymph node field (col. 8, lines 65-68, col. 9, lines 26-31, in particular), adjuvants such as cytokine and chemokines (col. 6-7 overlapping paragraph, in particular), antigens being lipid, anthrax

Art Unit: 1644

as bacterium, and influenza, rabies as virus (col. 6, lines 15-60, in particular) and the formulation with or without adjuvants (col 4, lines 51-60, in particular).

The '306 patent also teaches a single molecule acting both antigen and adjuvant such as cholera toxin (col. 11, lines 25-30, in particular) and the transdermal delivery method provides delivery of antigens to the immune system specialized immune cells underlying the skin (col. 4, lines 51-60, in particular).

Claim 81 is included because cleaning the surface with alcohol before application of medication.

Thus, reference teachings anticipate the claimed invention.

11. Claims 61-97 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 5,980,898 (IDS ref. VR).

The '898 patent teaches a transcutaneous immunization with a patch comprising an antigen and adjuvant (claims 1-9, in particular).

As the reference teaches the liposome containing antigen and adjuvant can be lyophilized (i.e. dry form, col. 11, lines 60-65, in particular) and application of said formulation to dry skin of subject (i.e. intact, col. 3, lines 42-43, col. 12, 44-46, in particular, option to "hydrate but not required" reads on dry), and effective length of time to induce immune response is inherent property as the intended use of the claimed invention is achieved, the reference teachings meet the limitations of claim 61.

The '898 patent further teaches the use of occlusive dressing covering the surface area larger than draining lymph node field (col. 3, lines 30-33, claims 2-5, in particular), includes adjuvants such as cytokine, chemokines (col. 9, lines 40-53, in particular), ADP-ribosylating exotoxin as an adjuvant (col. 9, lines 62-68, in particular).

The '898 patent also teaches antigens being lipid, bacteria such as anthrax, (col. 9, lines 6, in particular), viruses such as influenza, rabies, (col. 9, lines 20-21, in particular), attenuated live virus (col. 11, lines 41-46, in particular), multivalent antigen (col. 3, line 35, in particular), antigen specific responses (claims 1-

Art Unit: 1644

6, in particular) and a single molecule acting both antigen and adjuvant (i.e. cholera toxin col. 10, lines 27-32, in particular).

Thus, reference teachings anticipate the claimed invention.

12. Claims 61-97 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,797,276.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The '276 patent teaches a method of inducing immune response comprising applying a formulation comprising an antigen and an adjuvant in an occlusive dressing (claims 1-11, in particular). The '276 patent also teaches the antigenic formulation can be utilized with vehicles which encompasses powder (col. 8, line 25, in particular). Thus, the dry formulation is encompassed by the referenced formulation.

The '276 patent further teaches the antigen being anthrax, rabies virus, influenza, lipid, peptide or multivalent (col. 16-1, in particular), the antigen and adjuvant being a single molecule (col. 16, lines 38-42, in particular), LT or ADP-ribosylating exotoxin (col. 15, lines 15-48, in particular) and pretreating with alcohol (col. 24, Example 1).

The '276 patent also teaches immunizing influenza antigen and LT adjuvant (col. 41, lines 4-25, in particular) and occlusive dressing such as rayon applied to large surface are (col. 22, lines 15-32, in particular).

Thus, reference teachings anticipate the claimed invention.

Art Unit: 1644

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 61, 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,910,306 (IDS ref. VL) in view of U.S. Pat. No. 5,988,898 (IDS ref. VR)

The teachings of '306 patent have been discussed, supra.

The '306 patent does not teach a use of ADP-ribosylating exotoxin and heat-labile enterotoxin.

However, the '898 patent teaches use of ADP-ribosylating exotoxin and heat-labile enterotoxin with an antigen in transcutaneous immunization because ADP-ribosylating exotoxin target specialized antigen presenting cells, Langerhans cells, underlying the skin (cols. 5-6, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ADP-ribosylating exotoxin or heat-labile enterotoxin as taught by the '898 patent to the method to induce immune response with antigen-adjuvant formulation taught by the '306 patent.

One of the ordinary skill in the art would have been motivated to do so because the ADP-ribosylating exotoxin or heat-labile enterotoxin as taught by the '898 patent increases specificity of the immune response.

Art Unit: 1644

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 61-97 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 106-159 of copending Application No. 10/790,715, claims 1-40 of copending Application No. 11/334,349, claims 70-97 of copending Application No. 11/141,690. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '715, '349 and '690 applications teach a method of inducing antigen specific immune response comprising applying a formulation to skin of a subject where in the formulation comprises an antigen and adjuvant in dry form. The '715, '349 and '690 applications further teach various antigens being anthrax, influenza antigen or rabies virus, various adjuvant being DNA, cytokines, bacterial ribosylating exotoxins or tumor necrosis factor alpha.

Art Unit: 1644

The '715, '349 and '690 applications teaches the formulation is applied to skin with an occlusive dressing or through a patch.

17. Claims 61-83 are provisionally rejected under judicially created doctrine of double patenting over claims 89-107 of copending Application No. 11/514,462 and claims 102-105, 107-120 of copending Application No. 11/109,948. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '462 and '948 applications teach a method of inducing antigen specific immune response comprising applying a formulation to skin of a subject where in the formulation comprises an antigen and adjuvant in dry form. The '462 and '948 applications further teach various antigens being anthrax, influenza antigen or rabies virus, various adjuvant being DNA, cytokines, bacterial ribosylating exotoxins or tumor necrosis factor alpha.

18. Claims 61 and 84-86 are provisionally rejected under judicially created doctrine of double patenting over claims 19, 21-22 of copending Application No. 10/472,598. This is a provisional double patenting rejection since the conflicting claims have not yet been patented

Although the conflicting claims are not identical, they are not patentably distinct from each other because the both claims i teach a method of inducing antigen specific immune response comprising applying a formulation to skin of a subject where in the formulation comprises an antigen and adjuvant in dry form.


19. No claims are allowable.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 19, 2006

  
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